K112909

APR 30 2012

510(k) SUMMARY

1.0 Submitter Information:

Bausch + Lomb
1400 N. Goodman Street
Rochester, NY 14609
Contact: Tricia Garrett
Senior Specialist, Global Regulatory Affairs
1400 North Goodman Street
Rochester, NY 14609
(585) 338-6706 (office)
(585) 338-0702 (fax)
Tricia.m.garrett@bausch.com

2.0 Device Name:

Trade Name:	TBD
Common Name:	Soft (hydrophilic) contact lens care products Rigid Gas Permeable contact lens care products
Device Classification:	Class II (21 CFR 886.5918 & 21 CFR 886.5928)
Product Code	LPN, MRC

3.0 Predicate Device:

The predicate device is Ciba, Clear Care Cleaning and Disinfecting Solution cleared in K022687 on November 19, 2002 and K023455 on February 28, 2003.

4.0 Device Description:

Bausch + Lomb OCD04 3% Hydrogen Peroxide Cleaning and Disinfecting Solution is a sterile, buffered solution containing 3% hydrogen peroxide which contains a phosphonic acid stabilizer, potassium chloride, propylene glycol, carbamide (Urea), a citrate/phosphate buffer system, and poloxamer 181. A special lens case containing a platinum coated neutralizing disc is provided with the OCD04 Cleaning and Disinfecting Solution. The sterile solution is packaged in a plastic bottle with a tamper evident seal and labeled with a lot number and expiration date.

5.0 Intended Use:

Bausch + Lomb OCD04 3% Hydrogen Peroxide Cleaning and Disinfecting Solution is indicated for the daily cleaning, removal of protein deposits, disinfection, and storage of soft (hydrophilic) contact lenses (including silicone hydrogel) and rigid gas permeable contact lenses, as recommended by your eye care practitioner.

6.0 Description of Safety and Substantial Equivalence:

A series of preclinical testing was performed to demonstrate the safety and effectiveness of Bausch + Lomb OCD04 3% Hydrogen Peroxide Cleaning and Disinfecting Solution. A summary of the test results is provided below:

6.6 Biocompatibility

Bausch + Lomb OCD04 3% Hydrogen Peroxide Cleaning and Disinfecting Solution was evaluated for non-clinical safety in accordance with FDA Guidance for Contact Lens Solutions and Accessory Products, May 1997, as well as referencing several recognized testing Standards which were performed under Good Laboratory Practice regulations. Cytotoxicity, ocular irritation, and sensitization studies were completed for Bausch + Lomb OCD04 3% Hydrogen Peroxide Cleaning and Disinfecting Solution. The test results demonstrated that Bausch + Lomb OCD04 3% Hydrogen Peroxide Cleaning and Disinfecting Solution is non-cytotoxic, and not an ocular irritant or sensitizing agent.

6.7 Microbiology

A series of studies were conducted according to EN ISO 14729:2001/AMD.1:2010(E) *Ophthalmic optics – Contact lens care products – Microbiological requirements and test methods for products and regimens for hygienic management of contact lenses* and EN ISO 14730:2000(E) *Ophthalmic optics – Contact lens care products – Antimicrobial preservative efficacy testing and guidance on determining discard date.* The testing demonstrated Bausch + Lomb OCD04 3% Hydrogen Peroxide Cleaning and Disinfecting Solution meets the criteria for disinfection and preservative efficacy. Additionally, OCDO4 met the requirements of the ISO-FDA Regimen Procedure for Disinfecting Regimens for all nine lens materials tested.

6.8 Lens Compatibility

The results of lens compatibility studies demonstrate Bausch + Lomb OCD04 3% Hydrogen Peroxide Cleaning and Disinfecting Solution is compatible with soft contact lenses including, silicone hydrogel contact lenses and rigid gas permeable lenses.

6.9 Residual Peroxide and Area Under Curve

The results of the study demonstrate that the residual peroxide specification was met on cases cycled for the entire recommended use period, (35 cycles), as well as a safety margin out to 50 cycles. In addition, the area under curve for OCD04 3% Hydrogen Peroxide Cleaning and Disinfecting Solution, a measurement of the total peroxide exposure available to kill microorganisms, was greater than that for the control solution.

6.10 In-Vitro Protein Removal and Cleaning Efficacy

The protein removal ability of Bausch + Lomb OCD04 3% Hydrogen Peroxide Cleaning and Disinfecting Solution and predicate device Ciba Clear Care was evaluated using seven contact lens materials representing FDA groups I and IV and silicone hydrogel materials. The study evaluated the efficacy of the tested products against lenses deposited in vitro with lysozyme and subjected to a single cleaning / disinfection regimen. The results demonstrated that Bausch + Lomb OCD04 3% Hydrogen Peroxide Cleaning and Disinfecting Solution was substantially equivalent to the predicate device, Ciba Clear Care Cleaning and Disinfecting Solution.

In addition, the overall cleaning efficacy of the solution was evaluated through the determination of the critical micelle concentration (CMC). The surfactant concentration in the formulation was determined to exceed the CMC value.

7.0 Clinical Evaluation Summary:

A three-month multicenter, randomized, masked, parallel, bilateral clinical trial was conducted to support the substantial equivalence of Bausch + Lomb OCD04 3% Hydrogen Peroxide Cleaning and Disinfecting Solution when compared to Clear Care solution when used by habitual contact lens wearers to bilaterally clean and disinfect their contact lenses. Subject recruitment was open to currently adapted wearers of both soft and RGP lenses who met all of the inclusion criteria and none of the exclusion criteria.

There were significant differences over all follow-up visits between Bausch + Lomb OCD04 3% Hydrogen Peroxide Cleaning and Disinfecting Solution group and the Clear Care group in favor of the Bausch + Lomb OCD04 3% Hydrogen Peroxide Cleaning and Disinfecting Solution group for the following: *Comfort upon insertion* ($p = 0.017$), *Overall Comfort* ($p = 0.020$), and *Comfort at end of day* ($p = 0.009$).

Investigators evaluated the lenses for lens wetting while on the eye and found no significant differences between the B+L Peroxide Solution group and the Clear Care group. Other Investigator measures while lenses were on the eye included lens fitting characteristics (centration and movement). There were no significant differences between the B+L Peroxide Solution group and the Clear Care group for either fitting characteristic.

The safety of Bausch + Lomb OCD04 3% Hydrogen Peroxide Cleaning and Disinfecting Solution used with both a rub, rinse regimen and no-rub regimen is clinically acceptable and similar to Clear Care.

8.0 Substantial Equivalence Conclusion:

The cumulative results of laboratory, in vitro and in vivo testing sponsored by Bausch + Lomb demonstrate that the safety, efficacy and performance of Bausch + Lomb OCD04 3% Hydrogen Peroxide Cleaning and Disinfecting Solution are substantially equivalent to Ciba Clear Care Cleaning and Disinfecting Solution for soft contact lenses (including silicone hydrogels) as well as rigid gas permeable lenses.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

APR 3 0 2012

Bausch and Lomb
c/o Ms. Tricia Garrett
Senior Specialist, Global Regulatory Affairs
1400 North Goodman Street
Rochester, NY 14609

Re: K112909
Trade/Device Name: Bausch and Lomb OCD04 3% Hydrogen Peroxide Cleaning and Disinfecting Solution
Regulation Number: 21 CFR 886.5928
Regulation Name: Soft (hydrophilic) contact lens care products
Regulatory Class: Class II
Product Code: LPN, MRC
Dated: April 25, 2012
Received: April 26, 2012

Dear Ms. Garrett:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kesia Alexander

for

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K112909

Indications for Use Statement

510(k) Number (if known): K112909

Device Name: Bausch + Lomb OCD04 3% Hydrogen Peroxide Cleaning and Disinfecting Solution

Indications for Use:

Bausch + Lomb OCD04 3% Hydrogen Peroxide Cleaning and Disinfecting Solution is indicated for the daily cleaning, removal of protein deposits, disinfection, and storage of soft (hydrophilic) contact lenses (including silicone hydrogel) and rigid gas permeable contact lenses, as recommended by your eye care practitioner.

Prescription Use _____ AND/OR Over-The-Counter Use __✓____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear,
Nose and Throat Devices

510(k) Number K112909